DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 19, 2015

SpineCraft, LLC
Ms. Ami Akallal-Asaad
Vice President, Regulatory Affairs & Quality Assurance
777 Oakmont Lane
Westmont, Illinois 60559

Re: K150417
Trade/Device Name: ASTRA Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWP, KWQ
Dated: February 12, 2015
Received: February 18, 2015

Dear Ms. Akallal-Asaad:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150417

Device Name

ASTRA SPINE SYSTEM

Indications for Use *(Describe)*

The ASTRA Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudo-arthrosis).

The ASTRA Spine System is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation are L3 to S1), and for whom the device is intended to be removed after solid fusion is attained.

The ASTRA Spine System is also a sacral/iliac screw fixation system of the non-cervical spine indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudo-arthrosis).

When used in a percutaneous, posterior approach with AVANT Spine MIS instrumentation, the ASTRA Spine System is intended for non-cervical pedicle fixation for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudo-arthrosis, and failed previous fusion in skeletally mature patients . Levels of fixation are for the thoracic, lumbar and sacral spine.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
for the ASTRA Spine System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the ASTRA Spine System.

Date Prepared: February 12, 2015

1. Submitter:

SpineCraft, LLC
777 Oakmont Lane
Westmont, IL 60559 USA
Tel: 1 630-920-7300.
Fax: 1 630-920-7310

Contact Person:

Ami Akallal-Asaad
VP, Regulatory Affairs & QA
SpineCraft, LLC
a.asaad@spinecraft.com

2. **Trade name:** ASTRA Spine System

Common Name: Pedicle screw system

Classification Name: Pedicle screw spinal system per MNI 888.3070
Pedicle screw spinal system per MNH 888.3070
Pedicle screw spinal system per NKB 888.3070
Spinal interlaminal fixation orthosis per KWP 888.3050
Spinal intervertebral body fixation orthosis per KWQ 888.3060
Class III

3. Primary predicate or legally marketed device which is substantially equivalent:

- Expedium,Viper Spine System (K131802) DePuy Spine

4. Additional predicate devices:

- APEX Spine System (K062513 / K092825 / K102488 / K110906 / K132603) SpineCraft
- Xia Spinal System (K060748 / K071373 / K113666) Stryker
- Rogozinski (K954696) Smith Nephew
- Silhouette (K980288) Zimmer Spine
- MOSS MIAMI SS (K950697 / K000536) DePuy Spine
- Synergy VLS – open – (K940631) Cross Medical
- Ti Expedium 4.5 Spine System (K081252) DePuy Spine

5. **Description of the device:**

The ASTRA Spine System is a top loading, multiple component, posterior spinal fixation system which consists of rods, cannulated and non-cannulated monoaxial, uniplanar and polyaxial screws, hooks, iliac connectors, rod connectors, and cross connectors. Most of the components are available in a variety of sizes to more closely match the patient's anatomy.

Materials:
Titanium alloy
CoCr alloy

6. Substantial equivalence claimed to predicate devices

ASTRA Spine System is substantially equivalent to the APEX Spine System (K062513 / K092825 / K102488 / K132603), Expedium Viper Spine System (K090648 / K102701 / K131802), Xia Spine System (K060748 / K071373 / K113666), Rogozinski (K954696), MOSS MIAMI SS

(K950697 / K000536), Synergy VLS – open – (K940631), and Ti Expedium 4.5 Spine System (K081252) in terms of intended use, design, materials used, mechanical safety and/or performances.

7. **Intended Use:**

The ASTRA Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudoarthrosis).

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When used in a percutaneous posterior approach with AVANT MIS instrumentation, the ASTRA Spine System is intended for non-cervical pedicle fixation for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion in skeletally mature patients . Levels of fixation are for the thoracic, lumbar and sacral spine.

8. Non-clinical Test Summary:

The following tests were conducted:

- ASTM F1717, “Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model”. Testing included Static Compression Bending Tests, Static Torsion Tests and Dynamic Compression Bending Tests.
- ASTM F1798 “Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies used in Spinal Arthrodesis Implants”. Testing included Axial Gripping, Torsional Gripping, Static A-P, Static Flexion-Extension and Dynamic Flexion-Extension.

The results of this testing were compared to predicate systems, with the results being equal to or higher than the predicate systems.

9. Clinical Test Summary

No clinical studies were performed

10. Conclusions Nonclinical and Clinical

The ASTRA Spine System is substantially equivalent to the predicate devices in terms of indications for use, design, material, performance and function.